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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Requirements and Registration for the National Heart, Lung, and Blood Institute “Novel, Innovative Tools to Increase Public Awareness and Knowledge of Sickle Cell Disease Undergraduate Challenge”

Authority: 15 U.S.C. 3719

SUMMARY: The National Heart, Lung, and Blood Institute (NHBLI), a component of the National Institutes of Health (NIH) announces the “Novel, Innovative Tools to Increase Public Awareness and Knowledge of Sickle Cell Disease Undergraduate Challenge” to help address the lack of awareness about sickle cell disease and its associated complications and to improve successful implementation of effective interventions for sickle cell disease (SCD) in real world settings. In addition, by directing the Challenge at undergraduate students, the Challenge also aims to advance the field of implementation science through research training, mentoring, and highlighting the contributions of a new generation of undergraduate researchers using a systems science approach to address multi-faceted problems.

DATES: The Challenge begins [INSERT THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Submission Period: November 30, 2015 to March 7, 2016 11:59 pm PDT

Judging Period: March 14, 2016 to March 25, 2016

Winners Notified by email: April 5, 2016

Winners Announced: April 19, 2016

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SUPPLEMENTARY INFORMATION: Sickle cell disease is the most common genetic disorder in the United States. About 100,000 Americans are thought to be living with SCD, and each year another 1,000 babies are born with the disease. Sickle cell disease is an inherited disease that results in abnormal hemoglobin, the protein in human red blood cells that carries oxygen to all tissues in the body. Hemoglobin is essential for life. A specific single mutation in the gene (DNA) for hemoglobin, when inherited from both parents, causes SCD. The sickle hemoglobin distorts the shape of the red blood cell into a 'sickle' or crescent moon shape that flows poorly through small blood vessels.

This can cause problems in virtually any organ by reducing the delivery of oxygen and inflaming the surrounding tissue. These abnormal sickle cells usually die after only about 10 to 20 days (as compared to normal red blood cells that live about 120 days). Over time, organ damage occurs, possibly resulting in a stroke in the brain, kidney damage, or complications in other organ systems. SCD also causes significant pain in the affected tissues. This pain, which can begin in childhood, often escalates as adulthood approaches, severely affecting the quality of life of individuals with SCD. Sickle cell disease not only affects the individual but also his or her family and communities.

There is a lack of awareness about SCD and its associated complications among the general public and affected communities. This unawareness can contribute to the stigma associated with SCD, the lack of understanding of how the disease affects individuals and families' daily lives, and to less than optimal care experienced by many patients. To help address this problem, the NHLBI is launching the "Novel, Innovative Tools to Increase Public Awareness and Knowledge of Sickle Cell Disease Undergraduate Challenge" (the "Challenge") to incentivize the development of innovative information dissemination tools that may be used to (i) increase the general public's awareness of SCD; (ii) provide information on SCD and its complications to individuals, caregivers, families, and communities affected by SCD in an easily comprehensible manner; and (iii) improve patient care and health outcomes through the successful implementation of effective interventions for SCD in real world settings.

Statutory Authority of the Funding Source: The general purpose of the NHLBI is the conduct and support of research, training, health information dissemination, and other programs with respect to heart, blood vessel, lung, and blood diseases and with respect to

the use of blood and blood products and the management of blood resources. Sections 418 and 420 of the Public Health Service Act (42 U.S.C. 285b, 285b–2). This Challenge is consistent with and advances the mission of the NHLBI and its Center for Translation Research and Implementation Science. Among other things, this Center (1) plans, fosters, and supports an integrated and coordinated program of research to understand the multi-level processes and factors that are associated with successful integration of evidence-based interventions within specific clinical and public health settings such as worksites, communities, and schools; and (2) identifies and makes readily available to implementation and dissemination practitioners emergent knowledge about the late phases of translation research, especially for rapid and sustained adoption of effective interventions in real world settings. Funds for the Challenge have been provided by contributions to the NHLBI Gift Fund that are accepted under the authority established in Sections 231, 405(b)(1)(H), and 497 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 238, 284(b)(1)(H), and 289f).

Subject of the Challenge: Through this Challenge, the NHLBI is challenging undergraduate students to create novel, innovative information dissemination tools that may be used to increase the general public’s awareness of SCD, provide information on SCD and its complications (particularly pain) to individuals, caregivers, families, and communities affected by SCD in an easily comprehensible manner, and that may lead to rapid and sustained adoption of effective interventions for SCD in real world settings.

More specifically, the goals of the Challenge are to: 1) generate novel, innovative tools that may be used to increase public awareness and knowledge of SCD and associated complications that could potentially improve patient care; 2) advance the field

of implementation science through research training, mentoring, and highlighting the contributions of a new generation of undergraduate researchers using a systems science approach to address multi-faceted problems; and 3) encourage “team science” by providing undergraduate students valuable experiences to pursue science collectively as they engage in complex problem solving to improve health outcomes for SCD.

Rules for Participating in the Challenge: This Challenge is open to any “Student Team”, defined as a group of at least 3 and not more than 5 individuals each of whom is at least 18 years of age and currently enrolled as a full-time student pursuing a bachelor’s or associates degree.

The Student Team must also be trans-disciplinary, that is, composed of undergraduate students from diverse disciplines such as fine arts, performing arts, humanities, psychology, science, engineering, graphic design, IT (hardware, software), mathematics, statistics, environmental science, computational modeling and others.

To participate in and be eligible to win the Challenge, the Student Team must also:

- a. Have an individual from the teaching staff at the Academic Institution as a mentor to the team. The mentor should hold the position as a Professor, Associate Professor, Assistant Professor, Instructor, or a Teaching Assistant within the same Academic Institution as the Student Team. The teaching staff member can mentor only one team; however, a team may have more than one mentor (co-mentors may be located at a different institution);
- b. Agree to submit only one entry into this Challenge through one student

member of the Student Team appointed as “Team Captain” by that Student Team. The Team Captain will carry out all correspondence with NHLBI regarding the Student Team's entry. The Team Captain must be a citizen or permanent resident of the United States;

- c. On behalf of the Student Team, the Team Captain must certify the Student Team’s eligibility as part of the online submission process; and
- d. Agree that the Student Team’s mentor(s) shall not be eligible to share in the prize.

In addition, the following rules apply:

(1) To be eligible to win a prize under this Challenge, an individual or team –

- a. Shall have registered to participate in the Challenge under the rules promulgated by the Department of Health and Human Services (HHS), National Heart, Lung, and Blood Institute (NHLBI), Center for Translation Research and Implementation Science (CTRIS), as published in this Notice;
- b. Shall have complied with all the requirements set forth in this Notice;
- c. In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States;
- d. In the case of an individual, shall be a citizen or permanent resident of the United States. The Student Team Captain must be a citizen or permanent resident of the United States. However, the Student Team may include undergraduate students who are foreign citizens and/or non-permanent U.S. residents who are studying in the United States on a valid visa if such

students satisfy all the other criteria. Foreign students, if part of the winning Student Team, will not receive a monetary prize or be reimbursed for any costs associated with attending the annual NHLBI/National Sickle Cell Disease meeting (August 2016) to present and demonstrate the winning entry. As acknowledgement of their participation, however, the names of foreign students who are part of a winning Student Team will be listed among the winning team members when results are announced and at the annual NHLBI/National Sickle Cell Disease meeting;

- e. May not be a Federal entity;
- f. May not be a Federal employee acting within the scope of the employee's employment and further, in the case of HHS employees, may not work on their submission(s) during assigned duty hours;
- g. May not be an employee of the NIH, a judge of the Challenge, or any other party involved with the design, production, execution, or distribution of the Challenge or the immediate family of such a party (i.e., spouse, parent, step-parent, child, or step-child); and
- h. Agrees to abide by all applicable local, state, and federal laws, regulations, and policies.

(2) Federal grantees may not use Federal funds to develop their Challenge submissions unless use of such funds is consistent with the purpose of their grant award and specifically requested to do so due to the Challenge design.

(3) Federal contractors may not use Federal funds from a contract to develop their Challenge submissions or to fund efforts in support of their Challenge submission.

(4) Submissions must not infringe upon any copyright or any other rights of any third party.

(5) By participating in this Challenge, each individual and team agrees to assume any and all risks and waives any and all claims against the Federal government and its “related entities” (as defined in the COMPETES Act), except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from participation in this Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise.

(6) Based on the subject matter of the Challenge, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, property damage, or loss potentially resulting from Challenge participation, no individual or team participating in the Challenge is required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Challenge.

(7) By participating in this Challenge, each individual and team agrees to indemnify the Federal government against third party claims for damages arising from or related to Challenge activities.

(8) An individual or team shall not be deemed ineligible because the individual or team used Federal facilities or consulted with Federal employees during the Challenge if the facilities and employees are made available to all individuals and team participating in the Challenge on an equitable basis.

(9) By participating in this Challenge, each individual and team grants to the NIH and NHLBI an irrevocable, paid-up, royalty-free nonexclusive worldwide license to post, link to, share, sublicense, and display publicly on the Web the team’s submission. Each

individual and team will retain all other intellectual property rights in their submissions, as applicable.

(10) NIH and the NHLBI reserves the right, in its sole discretion, to (a) cancel, suspend, or modify the Challenge, and/or (b) not award any prizes if no entries are deemed worthy.

(11) Each individual (whether participating singly or in a group) or entity agrees to follow all applicable federal, state, and local laws, regulations, and policies.

(12) Each individual (whether participating singly or in a group) and entity participating in this Challenge must comply with all terms and conditions of these rules, and participation in this Challenge constitutes each such participant's full and unconditional agreement to abide by these rules. Winning is contingent upon fulfilling all requirements herein.

Registration and Submission Process for Student Teams: To register and enter a submission for this Challenge, the Team Captain can: Access the www.challenge.gov website and search for the “Novel, Innovative Tools to Increase Public Awareness and Knowledge of Sickle Cell Disease Undergraduate Challenge” where he or she will be redirected to an NHLBI-hosted website where:

- Team captain will register Student Team for the Challenge and submit its Team's entry in secure environment
- If the “Tool”, video, written entry, and slides are <25MB (total), they can be uploaded with the Team submission form
- If the “Tool”, video, written entry, and slides are >25MB (total), they must be hosted separately but available to Challenge Judges

- Teams can use available storage hosting services (including, but not limited to: Dropbox.com, Box.com, iCloud, Google Drive, etc...)
- Teams must include a link to hosted files in the Team submission (a field will be provided for this link)

Alternatively, the Team Captain can go directly to www.nhlbi.nih.gov or www.nhlbi.nih.gov/news/spotlight/fact-sheet/nhlbis-novel-innovative-tools-increase-public-awareness-and-knowledge-sickle-cell-disease page titled “Novel, Innovative, Tools to Increase Public Awareness and Knowledge of Sickle Cell Disease Undergraduate Challenge” and register for the Challenge and submit its Team’s entry in the same way as indicated above. The Team Captain will receive notification their entry has been received.

Submission Requirements: Each Student Team must submit a creative and innovative information dissemination tool, using any combination of media that is designed to reach out to the public to inform and increase awareness of sickle cell disease (SCD) and lead to rapid and sustained adoption of effective interventions for SCD in real world settings. Examples of such information dissemination tools include, but are not limited to, a video, a software application, a game, a website, a marketing campaign, a social media campaign, a grass roots campaign, or an exhibit. All materials must be written or composed in English. A complete submission is defined as follows:

- The fully functional tool or software application (“tool”) developed and tested by the Student Team. The Student Team must provide NHLBI with continuous access to the tool after submission and until winners are announced. As applicable, include a detailed description of the tool, instructions on how to install

and operate it, and system requirements. The tool must be designed for use with the most widely-available computing platforms: including, but not limited to: Windows-based Operating Systems; Mac OSX; iOS mobile computing platforms, and Android mobile computing platforms.

- A written entry (not to exceed 6 pages) that clearly and concisely includes the following:
 - A concise and informative title (150 characters or less).
 - A description of the tool, why it is innovative, the problem that the tool addresses, and the expected outcomes (goals) of using the tool.
 - A summary of the science and/or technology underlying the tool and its development.
 - A description of how the tool was tested among the population(s) of interest (e.g., urban/rural/socioeconomic populations, patients, clinicians, caregivers and/or researchers). Include a description of the study design and why it was selected to test the tool.
 - A description of the populations/communities involved in the test. Tools that include proposals on how to reach a range of users, including those with disabilities and underserved populations are encouraged.
 - Preliminary data describing the outcome(s) of testing the tool in the population(s) of interest and whether the tool met the anticipated goals. Were any outcomes unanticipated and what can be learned from them? What challenges or barriers were faced and what improvements could be made?

- A video (not to exceed two (2) minutes) that clearly articulates the problem and how the Student Team's submission addresses the problem. The video must deliver a clear and understandable message using non-technical language, have a unified voice, and emphasize new methods and insights not provided in the written submission to create a novel presentation while telling a compelling story, be visually striking, and edited to a high standard. Participants should be aware that this short video is required even if the tool described above is also a video.
- A set of seven (7) slides in PDF format that describes the submission. Address the judging criteria and describe the key features of the submission as they relate to the goals of the Challenge.

In addition, the submission must not use HHS, NIH, or NHLBI logos or official seals and must not claim endorsement.

Student Teams may be required to make their proposed solution compliant with Section 508 accessibility and usability requirements at their own expense. It can be costly to "retrofit" Section 508 accessibility standards if remediation is later needed. The HHS Section 508 Evaluation Product Assessment Template, available at <http://www.hhs.gov/web/508/contracting/technology/vendors.html>, provides a useful roadmap for developers. It is a simple, web-based checklist utilized by HHS officials to allow vendors to document how their products do or do not meet the various Section 508 requirements.

Amount of the Prize; Award Approving Official: The Award Approving Official will be the Director of the NHLBI. The NHLBI may select up to three winners to receive a monetary prize. Any money awarded to a winning Student Team will be distributed

equally among the Student Team's eligible undergraduate students. The Student Team Captain must be a citizen or permanent resident of the United States. Mentors and any team members that do not meet the applicable citizenship/residency requirements will not be eligible to receive any monetary prize award and will not be reimbursed for meeting registration or travel expenses to the annual NHLBI/National Sickle Cell Disease meeting (August 2016), as discussed below.

- 1st Prize - \$7,000 with up to an additional \$2,000 to reimburse the Student Team for eligible expenses to register for and travel to the annual NHLBI/National Sickle Cell Disease meeting to present and demonstrate its winning entry.
- 2nd Prize - \$5,000 with up to an additional \$2,000 to reimburse the Student Team for eligible expenses to register and travel to the annual NHLBI/National Sickle Cell Disease meeting to present and demonstrate its winning entry.
- 3rd Prize - \$3,000 with up to an additional \$2,000 to reimburse the Student Team for eligible expenses to register and travel to the annual NHLBI/National Sickle Cell Disease meeting to present and demonstrate its winning entry.
- Up to three Student Teams may also receive "Honorable Mentions" but no monetary prize, or support to register and travel to the annual NHLBI/National Sickle Cell Disease meeting will be provided. "Honorable Mentions" winning entries will be recognized on the NHLBI website and/or other media venues.

Payment of the Prize: Prizes awarded under this Challenge will be paid by electronic funds transfer and may be subject to Federal income taxes. HHS/NIH will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Basis upon Which Submissions Will be Evaluated: Five to seven Federal employees

will serve as judges. They could include members from any NHLBI Extramural Division/Office/Center, the Division of Intramural Research, and other NIH Federal employees. Each submission will be rated on the following criteria:

Significance (20 points): Potential impact and significance of the submission to improve public awareness and knowledge about SCD and associated complications and the successful implementation of effective interventions for SCD in real world settings. This must include scientifically accurate information.

Innovation (25 points): Submission is an innovative and creative information management tool that is:

- a. Different from existing technologies
- b. Designed for use on the most widely-available computing platforms: including, but not limited to: Windows-based Operating Systems; Mac OSX; iOS mobile computing platforms; and Android mobile computing platforms and
- c. Widely available to end-users (ease and breadth of dissemination)

Usability and design (25 points): User friendliness and user comprehension

- a. Appropriateness of user level and efficiency of use
- b. Tool generates the expected output leading to user satisfaction
- c. Evidence of co-design with and support from users of proposed tool (e.g., patient, family, caregivers, community, and healthcare providers)
- d. Appropriateness of images/messaging for the intended audience
- e. Clear, concise, and well-organized message
- f. Clarity of image and/or audio

Quality of pilot test and outcomes (30 points): Assess approach and feasibility

Approach:

- a. Research Objectives / Research Question / Literature Review
- b. Study Methods / Study Design
- c. Study participants, allocation of study participants, and intervention
(information management tool)
- d. Variables/Data Collection
- e. Statistical Analysis and Sample Size
- f. Outreach and Dissemination plan employed
- g. Results and discussion of pilot test outcomes

Feasibility:

- a. Dissemination plan employed likely to result in widespread use
- b. Based on the outcomes of the pilot, assess likelihood of full implementation
to succeed

The NHLBI reserves the right to disqualify a submission if the tool fails to function as expressed in the description provided by the submitting Student Team or if the tool provides inaccurate or incomplete information. Submissions must be free of malware. The NHLBI may test the tool to determine whether malware or other security threats may be present and reserves the right to disqualify the submission if, in NHLBI's judgment, the tool may damage government or others' equipment or operating environment.

Challenge Judges:

Senior Advisor, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute

Clinical Trials Specialist, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute

Program Director, Division of Lung Diseases, National Heart, Lung, and Blood Institute

Deputy Director, Office of Translational Alliances and Coordination, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute

Staff member, Office of Science Policy, Engagement, Education and Communications, National Heart, Lung, and Blood Institute

Staff member, Center for Translation Research and Implementation Science, National Heart, Lung, and Blood Institute

Deputy Chief, Education and Community Involvement Branch, National Human Genome Research Institute

Dated: October 2, 2015.

Gary H. Gibbons, M.D.

Director, National Heart, Lung, and Blood Institute

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